# EXHIBIT 3

No. 23-_____

# In the United States Court of Appeals for The Third Circuit

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION

ON APPEAL FROM THE U.S. DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY
THE HONORABLE ROBERT B. KUGLER, NO. 19-2875

## NDEA DEFENDANTS' PETITION FOR PERMISSION TO APPEAL PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 23(f)

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## CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1 and L.A.R. 26.1.0, the NDEA Defendants provide the following corporate disclosure statements:

- Mylan Pharmaceuticals Inc., Mylan Laboratories Ltd., and Mylan N.V. state that they are wholly owned indirect subsidiaries of Viatris Inc., a publicly held company (NASDAQ: VTRS). No publicly held entity owns 10% or more of Viatris Inc.'s stock.
- Aurolife Pharma LLC is a wholly owned subsidiary of Aurobindo Pharma USA, Inc., which is wholly owned by Aurobindo Pharma Ltd. No publicly held corporation owns 10% or more of Aurobindo Pharma Ltd's stock.

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## INTRODUCTION

The district court certified a class of millions of plaintiffs suing 31 different defendants related to 428 different valsartan-containing drugs ("VCDs") that plaintiffs agree provided life-saving benefits by controlling their hypertension. D.2008-5. Plaintiffs seek relief under the laws of 52 different states and territories for drugs manufactured by different companies, at different manufacturing facilities, through different manufacturing processes, over a six-year period. To address the staggering number of individualized issues posed by this case, the district court certified *111 subclasses* of plaintiffs seeking damages for economic loss, plus *another two* classes seeking medical monitoring. No other court has upheld class certification under similar facts.

This Court's intervention is plainly warranted. The district court's decision is contrary to well-established Third Circuit law, which requires a rigorous analysis of Rule 23's requirements—an analysis absent from the decision. *See In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 316-21 (3d Cir. 2008). Indeed, this Court has questioned whether medical monitoring classes could *ever* be certified, given the individualized issues posed by medical treatments. *See Gates v. Rohm & Haas Co.*, 655 F.3d 255, 268 (3d Cir. 2011). Yet the district court certified the medical monitoring classes here without carefully analyzing those individualized issues.

The district court likewise certified two economic loss classes without a rigorous analysis of whether individual issues would overwhelm common issues at trial—and without considering individualized differences between defendants. Instead, the district court concluded that the predominance requirement necessitated little more than a "'legal cite-checking' initiative" to confirm "the correctness of the state law standards that plaintiffs advance." Attachment A, D.2261 ("Opinion") 40; Attachment B, D.2262 ("Order").

This Court should grant the petition to reverse these legal errors. There is no way to try a case of this magnitude before a jury in a way that protects defendants' legal rights. It would take an entire week just to *read* the jury instructions. This Court should also grant the petition given the immense settlement pressures created by certification.

Mylan and Aurobindo (together, the "NDEA Defendants") join and incorporate by reference the 23(f) petitions filed by the other manufacturer defendants, the wholesaler defendants, and the pharmacy defendants, and file this separate petition to highlight individual differences between specific defendants that provide further reasons why this Court should grant review. For example, the district court certified medical monitoring classes that include Mylan and Aurobindo, yet the program that plaintiffs propose monitors for many cancers that the district court concluded the NDEA Defendants' products—which contained

even lower trace amounts of a different impurity than other defendants' products—*could not cause*. The district court did not even address this critical distinction between defendants. Given the many flaws in the district court's decision, this Court should grant the petition and reverse.

## STATEMENT OF THE CASE

Between July 2018 and January 2019, 428 different VCDs were recalled due to the potential presence of trace amounts of two nitrosamine impurities, N-Nitrosodimethylamine ("NDMA") and N-Nitrosodiethylamine ("NDEA"). The recalls were conducted voluntarily after certain batches of VCDs were found to contain nitrosamine impurities above the FDA's "conservative, protective limit," *In re Zantac (Ranitidine) Prod. Liab. Litig.*, --- F.Supp.3d ----, No. 20-MD-2924, 2022 WL 17480906, at *2 (S.D. Fla. Dec. 6, 2022), which the FDA recognizes does not reflect a "realistic indication of the actual risk." FDA, M7(R1) Assessment and Control of DNA Reactive (Mutagenic) Impurities 5-6 (2018).

Nitrosamines are ubiquitous in air, water, food, cosmetics, and tobacco products, D.1717-1 at 10; D.1714-1 at 3; D.2009-26, at 8, and "there is no scientist outside this litigation" who has concluded VCDs cause cancer in humans at the trace levels at issue here. *Zantac*, 2022 WL 17480906 at *4.[1] Nevertheless,

[1] The district court in *Zantac*, another case involving nitrosamine impurities, excluded all of plaintiffs' general-causation experts and granted summary

*(cont'd)*

plaintiffs filed over 1,000 personal-injury actions, in addition to three nationwide class actions, on the theory that exposure to VCDs can cause 13 types of cancer within months of exposure. D.706.

Plaintiffs' suits named many different companies, including manufacturers, wholesalers, pharmacies, repackagers, and FDA liaisons. The VCDs differed in several important respects. VCDs manufactured using Mylan's active pharmaceutical ingredient, for example, contained trace amounts of NDEA, but did not contain NDMA above FDA's allowable limits. Similarly, Aurobindo's VCDs contained only NDEA but not NDMA, and only certain lots of Aurobindo's VCDs were recalled—the rest were not as any nitrosamines were below allowable limits.

The litigation was centralized for coordinated multi-district proceedings in the U.S. District Court for the District of New Jersey before Judge Kugler. Plaintiffs moved for certification of three types of classes: (1) consumer economic loss; (2) third-party payor ("TPP") economic loss; and (3) medical monitoring. The consumers and TPP economic loss classes claim the VCDs they purchased or reimbursed were worthless due to the alleged presence of nitrosamines. D.2010 at 1. Plaintiffs also moved to certify a class seeking medical monitoring as a cause of

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judgment in a 341-page memorandum. 2022 WL 17480906. The district court here did not exclude any of plaintiffs' general-causation experts or even issue a written *Daubert* opinion. *See* D.1958 (three-page *Daubert* order); D.2209-1 (seeking reconsideration thereof with reference to *Zantac*).

action under the laws of 28 states, D.2012 at 2, as well as a class seeking medical monitoring as a form of relief under the laws of 49 states and territories, *id.* Both medical monitoring classes were defined to include individuals who "consumed a Lifetime Cumulative Threshold ["LCT"] of NDMA, NDEA, or both" in VCDs. Opinion 68. The district court recognized that plaintiffs' purported "Lifetime Cumulative Threshold" did not create a purely objective standard for ascertainability and that plaintiffs failed to explain how that threshold was derived or related to an increased risk for developing any cancer. *Id.* Nevertheless, the Court held that the threshold was "scientifically-rigorous-enough." *Id.* at 69.

The district court granted certification of essentially all of plaintiffs' proposed classes.[2]

## QUESTIONS PRESENTED

1. Whether the district court erred in certifying medical monitoring classes despite this Court's precedent casting doubt as to whether the need for medical monitoring can ever be shown through common proof and despite individualized differences among *both plaintiffs and defendants* with respect to whether medical monitoring is necessary.

[2] The district court denied without prejudice certification of a Rule 23(b)(2) medical monitoring class.

2. Whether the district court erred by concluding that Rule 23's predominance requirement could be met by creating 111 economic loss subclasses.

3. Whether the district court erred by failing to conduct the rigorous analysis required by Rule 23 to determine whether individual issues would overwhelm common issues at a trial involving millions of plaintiffs, 31 different defendants, and 428 different products, conducted under 52 jurisdictions' laws.

4. Whether the settlement pressure created by the district court warrants this Court's review.

## RELIEF SOUGHT

The NDEA Defendants request permission to appeal from the district court's order pursuant to Federal Rule of Civil Procedure 23(f) and ask the Court to reverse class certification.

## REASONS FOR GRANTING THE PETITION

Interlocutory review under Rule 23(f) is appropriate if "a class certification ruling is likely erroneous" or creates "inordinate" settlement pressure, or "when the appeal implicates novel or unsettled questions of law." *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 164 (3d Cir. 2001). The ruling below satisfies all three criteria. The decision is manifestly erroneous, relies on the novel use of more than 111 subclasses to try claims under 52 jurisdictions' laws, and places inordinate settlement pressure on defendants. There is no way to try a case

of this magnitude against 31 different defendants in a way that protects defendants' right to a fair trial.

## I. THE COURT SHOULD GRANT REVIEW TO REVERSE THE MANIFESTLY ERRONEOUS CERTIFICATION OF THE MEDICAL MONITORING CLASSES.

The district court *agreed* that the "scientific community itself cannot tease out a single, individual cause of cancer from a lifetime of nitrosamine exposure from various sources" or "determine the cause of an inflection point making one's likelihood of developing cancer more and more probable." Opinion 64-65. Yet it nevertheless certified two medical monitoring classes, which "means that each class member will get various medical tests on a spelled out, regular basis to monitor for esophageal, stomach, colorectal/intestinal, liver, lung, bladder, blood, pancreatic, and prostate cancer, cancers linked to NDMA and NDEA exposure." *Id.* at 59.

The district court did not analyze—as required by this Court's precedent—whether "causation and medical necessity . . . require individual proof" for each plaintiff, such that the Rule 23(b)(2) medical monitoring class "founder[s] for lack of cohesion." *Gates*, 655 F.3d at 264, 270. Nor did the district court analyze—as required by this Court's precedent—whether "individual issues," such as each individual's amount of exposure, risk of disease, availability of early detection for

particular diseases, and medical necessity of monitoring, prevented certification of the Rule 23(b)(3) monitoring class. *Id.* These manifest errors require reversal.

This Court has questioned whether "the necessity for individuals' medical monitoring regimes can" *ever* "be proven on a class basis." *Gates*, 655 F.3d at 268; *see Barnes v. American Tobacco Co.*, 161 F.3d 127, 145 (3d Cir. 1998). That is particularly true here, where plaintiffs seek a class trial against *31 different defendants* involving *428 different products* with varying levels of nitrosamine impurities (if any). Plaintiffs assert that any person who used an arbitrary threshold (measured in months) of VCDs is at a heightened theoretical risk of cancer, justifying monitoring. But plaintiffs had vastly different exposures to NDMA or NDEA, depending on their dose, duration of exposure, and the specific lots of VCD (or multiple VCDs) used. This creates at least three kinds of individualized issues that prevent certification.

*First*, the VCDs were manufactured by different companies, in different facilities, with different processes. Some contain NDMA but not NDEA. Some, like the NDEA Defendants' VCDs, contain NDEA but not NDMA. Some lots of VCDs contain *no* nitrosamines. And the nitrosamine content varies, sometimes by a thousand-fold, from batch-to-batch. Calculation of a Lifetime Cumulative Threshold for each class member, many of whom likely consumed VCDs from multiple Defendants, is a hugely complex, individualized issue. These are crucial

individualized differences among defendants' products that should have prevented certification.[3]

For example, the VCDs manufactured by the NDEA Defendants contained only NDEA above the FDA's allowable intake level, not NDMA. The district court determined that NDEA impurities in VCDs allegedly increase the risk of *only one* of those cancers—pancreatic[4]—and there is no way to reliably screen for pancreatic cancer.[5] Yet plaintiffs who took only Mylan or Aurobindo's products

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[3] The Court also erred by failing to address whether plaintiffs who took Aurobindo products with NDEA impurities can be ascertained. Aurobindo recalled only VCDs with NDEA impurities, and only those batches of VCDs with NDEA impurities above the FDA's acceptable intake level. By using National Drug Codes to identify recalled VCDs, plaintiffs put forth no basis for ascertaining which plaintiffs consumed recalled Aurobindo VCDs and which plaintiffs consumed non-recalled VCDs. Since not all VCDs with the same National Drug Code are from the same batch or lot, it is impossible to determine whether a plaintiff consumed a recalled Aurobindo VCD by National Drug Code alone. Plaintiffs thus cannot ascertain which plaintiffs should be part of the certified classes, in violation of controlling precedent.

[4] Per the district court's *Daubert* rulings on general causation, plaintiffs' experts can offer the opinion that NDEA exposure through VCDs is associated with an increased risk of only pancreatic cancer. D.1958. Plaintiffs' experts relied on a solitary dietary study, Zheng—in which the authors did not reach any conclusions on causation, D.2209-1 at 17-19—to link NDEA to the human cancers at issue. D.1716-1 at 22-24. At the class stage, plaintiffs relied on just two of their general-causation experts, Drs. Panigrahy and Madigan, to support their proposed Lifetime Cumulative Threshold. D.1750 at 4. Both experts' opinions on NDEA were expressly limited to pancreatic cancer. D.1958.

[5] Plaintiffs' medical monitoring expert, Dr. Kaplan, proposes the use of an experimental blood test to screen for pancreatic cancer that has not been approved by the FDA. D.2024-1 at 2.

are nevertheless included in a class that screens for 9 different cancers—even though there is no basis for monitoring such plaintiffs. D.2012 at 19-20; D.2009-25 at 17. The district court's certification of the medical monitoring classes is irreconcilable with its exclusion of plaintiffs' class experts' opinions that NDEA causes cancer other than pancreatic cancer.

*Second*, medical monitoring class members have vastly different medical histories and prior carcinogen exposure. Plaintiffs who smoke or are over age 50 may *already* be receiving monitoring for increased cancer risk. D.2012 at 17. As plaintiffs' expert acknowledged, testing and treatment decisions in a clinical setting are based on the "patient's specific situation," including medical history, comorbidities, and the patient's subjective desires. D.2009-7, Ex. 50, 51:19-52:11. Indeed, some of plaintiffs' screening proposals (such as colonoscopies and CT scans) pose health risks that *exceed* the alleged risk posed by nitrosamine exposure in VCDs and are not medically recommended for plaintiffs with certain health conditions. *See* D.2009-16, 27-33; D.2009-25, 16, 18. This too creates an individualized issue that should have prevented certification. *See Gates*, 655 F.3d at 269.

These individualized issues are why "[l]ower courts almost unanimously have rejected" certification of medical monitoring classes. *In re Fosamax Prods. Liab. Litig.*, 248 F.R.D. 389, 396 & n.8 (S.D.N.Y. 2008) (collecting cases). *Gates*

held that a plaintiff must show a single exposure that "would create a significant risk of contracting a serious latent disease for all class members." 655 F.3d at 267; *see id.* at 268 (class treatment improper where plaintiffs failed to "account[] for the age of the class member being exposed, the length of exposure, other individual factors such as medical history"). Yet the district court *did not even evaluate* these crucial individual issues.

To the contrary: Although the court noted that "defendants raise doubts whether a proposed medical monitoring program is medically necessary," Opinion 65, it never analyzed those concerns or explained how they could be sufficiently overcome. *See Gates*, 655 F.3d at 267; *Barnes*, 161 F.3d at 145 (monitoring class could not be certified because "plaintiffs cannot prove causation by merely showing that smoking cigarettes causes cancer and other diseases" but must also show that "nicotine manipulation caused *each individual plaintiff* to have a significantly increased risk of contracting" disease [emphasis added]). That was manifest error.

*Third*, as the other manufacturer defendants' petition explains, the court failed to consider whether legal variations among state laws prevented certification. Numerous courts have recognized that fundamental "[d]ifferences in state laws on medical monitoring" prevent certification. *See, e.g.*, *In re St. Jude Med. Inc.*, 425 F.3d 1116, 1122 (8th Cir. 2005); *In re NHL Players' Concussion*

*Injury Litig.*, 327 F.R.D. 245, 260, 266 (D. Minn. 2018). The district court attempted to address this problem by creating a table listing differences in state laws. Opinion 61. But creating a table only highlights those differences and does not obviate them, much less demonstrate that Rule 23's requirements are met.

The district court's decision to certify two medical monitoring classes is contrary to the decisions of this Court and many others. Neither plaintiffs nor the district court cited a single case like this one—involving different drugs manufactured by different companies using different processes, with different alleged impurities and levels of exposure, ingested by different plaintiffs with different medical histories for different amounts of time—where certification was upheld.

## II. THE COURT SHOULD GRANT REVIEW TO REVERSE THE DISTRICT COURT'S MANIFESTLY ERRONEOUS CONCLUSION THAT INDIVIDUALIZED ISSUES COULD BE ADDRESSED THROUGH 111 CONSUMER AND THIRD PARTY PAYOR SUBCLASSES.

This Court's review is also warranted to correct a second manifest error: The district court certified two classes of economic loss plaintiffs—despite the individualized issues created by plaintiffs' attempt to litigate five separate causes of action under 52 separate jurisdictions' laws—by creating *111 different subclasses*. Yet the district court never analyzed whether creating 111 subclasses in fact addressed the individualized questions created by the many different state

laws at issue, much less explained how a jury could possibly evaluate the claims of each of those subclasses in a way that protects defendants' right to a fair trial.

Nationwide classes—even those pursuing only one cause of action—are poor candidates for class treatment because legal differences will generally "cast a long shadow over any common issues of fact." *Pilgrim v. Universal Health Card, LLC*, 660 F.3d 943, 946 (6th Cir. 2011). This case presents even greater complications, spanning 52 jurisdictions and alleging five causes of action against different defendants who sold different products manufactured using different processes. Multiplied together, these variations lead to hundreds of different legal questions for a jury.

The district court concluded—contrary to the vast weight of authority—that these individualized questions could be cured through subclasses. *See* Opinion 22. But "'[s]ubclass' is not a magic word that remedies defects of predominance." *Elson v. Black*, 56 F.4th 1002, 1007-08 (5th Cir. 2023). Plaintiffs retain the burden to show "*how* [the] proposed subclasses would alleviate … obstacles to certification." *Id.*; *Grandalski v. Quest Diagnostics Inc.*, 767 F.3d 175, 183 (3d Cir. 2014) ("significant burden to demonstrate that grouping is a workable solution").

Plaintiffs did not meet that burden. Plaintiffs proposed a single trial before a single jury, but a trial of this magnitude would be unmanageable on every

dimension. The 111 certified subclasses are *more than double* the amount deemed unfeasible by other courts. *See Pilgrim*, 660 F.3d at 946; *Elson*, 56 F.4th at 1006-07; *In re LIBOR-Based Fin. Instruments Antitrust Litig.*, 299 F. Supp. 3d 430, 547-48 (S.D.N.Y. 2018) (finding "little appropriate about the establishment of dozens, if not hundreds, of subclasses" and citing Second Circuit's statement that seven subclasses was "surely beyond the point at which subclassing must end" [internal quotation marks and alterations omitted]).

Indeed, there are so many subclasses that it took plaintiffs *67 pages to list them*. D.1747-1; D.1747-2. These subclasses advance five legal theories against 31 defendants from 10 different corporate families, spanning four different levels of the supply chain—Active Pharmaceutical Ingredient manufacturing, finished-dose manufacturing, wholesale, and retail. There is no conceivable way for jurors to keep track of that many claims against that many defendants.

As other courts have held, "[i]f more than a few of the laws of the fifty states differ, the district judge would face an impossible task of instructing a jury." *In re Am. Med. Sys.*, 75 F.3d 1069, 1085 (6th Cir. 1996). That is true here, where the model jury instructions for plaintiffs' claims total approximately *1,200 pages*. *See* D.2008, Apps. K, L, M, N. If the judge read one page every two minutes, it would take *40 hours* to instruct the jury. No juror could comprehend that much information, much less account for the "nuances" of the "multiple standards" and

return an intelligent verdict. *Marshall v. H&R Block Tax Servs.*, 270 F.R.D. 400, 408 (S.D. Ill. 2017); *see Woodard v. Labrada*, No. 16-cv-189, 2021 WL 4499184, at *40 (C.D. Cal. Aug. 31, 2021) (denying certification where "numerous different jury instructions" would be unmanageable and prejudice defendants).

There is no way to try the claims of all 111 subclasses in a way that protects defendants' rights. The district court acknowledged that a trial with this many subclasses might be "onerous and [require] a steep climb of effort," but concluded that certification was appropriate, given the court's "experience with the MDL." Opinion 24. No amount of experience on the part of the district court would equip a jury to decide the individual claims of 111 different subclasses, including those against Mylan and Aurobindo, which involve a different nitrosamine, at different quantities, and a different cancer claim. Defendants have the right to a fair trial by a properly instructed jury that can comprehend those instructions. The certification of the sprawling class here—with more subclasses than any case defendants have located—infringes on that basic right.

## III. THE COURT SHOULD GRANT REVIEW TO REVERSE THE DISTRICT COURT'S MANIFESTLY ERRONEOUS CONCLUSION THAT COMMON QUESTIONS PREDOMINATE.

This Court should grant review for a third reason: The district court held that because it could divide plaintiffs' legal claims into subclasses, Rule 23's requirements were met. But the district court failed to consider whether

individualized issues *within* each subclass overwhelmed common questions. That failure is particularly problematic in a case like this one, where different defendants manufactured different products, taken at different doses, which contained different levels of different nitrosamine impurities. Indeed, the NDEA Defendants will have individual defenses at trial related to their specific products—which contained only NDEA at such low levels that *no named class representative* can satisfy plaintiffs' proffered "Lifetime Cumulative Thresholds" based solely on consumption of Mylan's or Aurobindo's products. *See, e.g.*, D.2008 at 13-14. The district court's failure to consider these individualized differences led to its erroneous ruling and justifies this Court's intervention.

Certification is proper only "'if the trial court is satisfied, after a rigorous analysis, that the prerequisites' of Rule 23 are met," with all "[f]actual determinations supporting Rule 23 findings . . . made by a preponderance of the evidence." *Hydrogen Peroxide*, 552 F.3d at 307, 309 (citation omitted); *see In re Lamictal Direct Purchaser Antitrust Litig.*, 957 F.3d 184, 190-91 (3d Cir. 2020) (requiring a "rigorous analysis" of the "facts, evidence, and arguments"). The district court did not perform that rigorous analysis. Instead, it "researched the correctness of the state law standards that plaintiffs advance," explaining that the court's "'legal cite-checking' initiative" was "a key pathway to confirm that predominance has been deconstructed properly." Opinion 40; *see id.* at 23 ("[T]he

Court has chosen a practical approach to predominance: to confirm that subclasses aptly map the reality of state law variation and factual variability.").

That is wrong. Rule 23 does not ask district courts to create a "chart of state law jurisprudence." *Id.* 40. It requires district courts to rigorously analyze whether common questions will predominate. *See Hydrogen Peroxide*, 522 F.3d at 321-22. If the district court had properly performed that analysis, it would have denied certification.

*First*, as the other manufacturer defendants' brief explains, plaintiffs' state-law claims require plaintiffs to prove different elements for each plaintiff, depending on the state, including proof of a defect, materiality, reliance, causation, injury, and damages. Those are individualized issues that would overwhelm common issues at trial. Reliance, to take one example, makes class-wide proof "a near-impossibility" under certain states' laws because proof of reliance requires individualized inquiry. *Brown v. Electrolux Home Prods., Inc.*, 817 F.3d 1225, 1237 (11th Cir. 2016) (citation omitted).

Those individualized questions are compounded by the 428 VCDs at issue in this case. The VCDs manufactured by Mylan and Aurobindo, for example, contained only NDEA. The FDA has estimated the *theoretical* excess risk of developing cancer from exposure to NDEA in VCDs taken at the highest dose every day for four years—which goes well beyond the exposure claimed by any

class representative concerning the NDEA in Defendants' products—is 1 in 18,000. D.2009-12, Ex. 105. And, as the district court held, there is no evidence of a causal association between NDEA exposure and 12 of the 13 cancers at issue. D.1958. To determine whether a class member would have continued to take Mylan or Aurobindo's VCDs in light of this alleged theoretical, *de minimus* risk requires an individualized inquiry. The district court's decision to certify 111 subclasses does not address these "individualized factual inquiries," which prevent certification. *Farrar & Farrar Dairy, Inc. v. Miller-St. Nazianz*, 254 F.R.D. 68, 75-76 (E.D.N.C. 2008).

Proof of injury and damages likewise requires individualized inquiry. Both consumers and TPPs must show that they would have *paid less* in the absence of the alleged impurities to establish injury and damages. But many consumers have insurance, and thus pay the *same amount* (such as a co-pay) for pharmaceutical products. Those consumers could not possibly have suffered injury. Other consumers have different payment arrangements that affect whether they suffered any injury. And if VCDs had been unavailable, TPPs may have paid for "alternative hypertension medications," which might have been more expensive. D.2040-11 at ¶ 63; D.2199. Determining which TPPs would have paid for which alternative medications requires TPP-by-TPP, if not patient-by-patient, analysis.

Plaintiffs attempted to get around this problem by submitting expert testimony—disputed by defendants' experts—that all VCDs containing impurities were economically worthless. *See* D.2040-1 at 2. The district court, however, refused to decide that question. Opinion 23. According to the court, "choosing one theory over the other [would] drive[] a decision as to predominance that bounds too deeply into the province of the factfinder." *Id.* That, too, was wrong. This Court has expressly held that a district court "may not decline to resolve a genuine legal or factual dispute" relevant to class certification "because of concern for an overlap with the merits." *Hydrogen Peroxide*, 552 F.3d at at 324.

A proper consideration of the experts' opinions would have led the court to deny certification. Other courts that have resolved similar disputes have rightly concluded that assigning no value to a medication that "benefi[ted] many patients" is "not a defensible position." *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61, 69 (S.D.N.Y. 2002) (rejecting use of no-value presumption and denying class certification); *see, e.g.*, *City Center Periodontists, P.C. v. Dentsply Int'l, Inc.*, 321 F.R.D. 193, 212 (E.D. Pa. 2017) (predominance lacking because "it is no[t] true that [the dental device] had 'zero value'").[6]

[6] The court's exclusion of defense expert opinions relating to worthlessness and other matters compounds its error in granting certification. For example, the court erroneously excluded the opinion of Dr. Clevenger relating to pharmaceutical equivalence (which bears on economic value) in part because he did not consider

*(cont'd)*

*Second*, plaintiffs' state-law claims apply differently depending on which specific batch of VCD each plaintiff ingested—creating yet another individualized issue that defeats certification. This case involves *428* distinct VCDs. The VCDs were synthesized by different manufacturers, using different chemical processes, which are alleged to have created different nitrosamine impurities. D.1748 at 8-38. On top of that, VCDs were synthesized in different batches, with different amounts of NDMA or NDEA, *if any*, in each batch, D.2008 at 2-10, necessitating a batch-by-batch inquiry for *each plaintiff*, given plaintiffs' theory that VCDs were economically worthless when they contained nitrosamines, but not otherwise.

A jury could find one defendant's manufacturing process to be defective or negligent and another proper. Each Active Pharmaceutical Ingredient manufacturer's root cause analysis was different. In some instances, a nitrosamine was found to form during the primary synthetic pathway; in others, the impurity

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"guidance" available on the United States Pharmacopeia's website. Opinion 76. It also excluded Dr. Clevenger's opinion concerning the decrease in nitrosamine content throughout Aurobindo's finished drug manufacturing process because Dr. Clevenger did not "include a comparison of Aurobindo's initial test results either with Aurobindo's second results or with the FDA subsequent test results." *Id.* These are issues for cross examination, not a basis for exclusion.

As another example, the court excluded several of Dr. Lambert's opinions, including his opinion that VCDs were bioequivalent with the Reference Listed Drug and therefore not "worthless." *Id.* at 82. The court erroneously called this an "unqualified economics opinion," even though his opinion was based on his pharmaceutical training and expertise, not economics.

developed outside the main process used to make valsartan. *Id.* And a jury could find that one plaintiff's ingestion of a specific batch of VCD did not pose any increased risk of cancer, given the amount of NDMA or NDEA—if any—in that specific batch.

Moreover, plaintiffs have sued different finished-dose manufacturers, which allegedly incorporated valsartan with impurities into consumer-ready drugs. Each used different suppliers and took different steps to ensure purity. *Id.* Courts have rejected far simpler class actions, recognizing that no jury could parse so many factual variations. *See, e.g.*, *In re Bridgestone/Firestone, Inc*, 288 F.3d 1012, 1019 (7th Cir. 2002) (granting 23(f) review and reversing certification in part because case involved "67 specifications" of tires); *In re Ford Motor Co. Vehicle Paint Litig.*, 182 F.R.D. 214, 220 (E.D. La. 1998) (denying certification in case involving "different models of vehicles, made of different materials, painted … at different plants, using different paint formulae"); *City of St. Petersburg v. Total Containment, Inc.*, 265 F.R.D. 630, 636 (S.D. Fla. 2010) (predominance not met given "different models … manufactured by different companies at different times and at different locations"). The individualized facts here, which differ for each plaintiff and each defendant, prevent class treatment.

This Court's intervention is plainly warranted. The district court did not conduct the basic inquiry required by Rule 23. Listing state laws in a chart is not

sufficient. Much more is required—particularly in a case, like this one, where there are so many different kinds of plaintiffs *and* defendants, and so many different variations in state law.

## IV. THE COURT SHOULD GRANT REVIEW GIVEN THE INORDINATE SETTLEMENT PRESSURE.

This Court should also grant the petition given the inordinate settlement pressure placed on defendants by virtue of the district court's class certification ruling, including its certification of *111* different subclasses. *See Laudato v. EQT Corp.*, 23 F.4th 256, 261 (3d Cir. 2022) (granting 23(f) petition where order could "reasonably" be "read . . . as an attempt to nudge [the parties] toward settlement"). The district court has made no secret of its interest in settlement. At the first case management conference, it announced its intention to "talk[] to [the parties] early and often about settlement possibilities." D.77, Mar. 27, 2019 Hr'g Tr. 28:13-29:8. It imposed on the parties—over defendants' objections, D.1821—the unusual obligation to retain separate settlement counsel. D.1848, Jan. 5, 2022 Hr'g Tr. 20:12-22:20. The court told the parties that it intended to instruct settlement special masters to "begin aggressively scheduling some sessions," in advance of class certification briefing. D.1948, Feb. 28, 2022 Hr'g Tr. 43:2-13. The court also expressed its view that "given the size of some of the defendants, [a settlement] may not even be material to your bottom line." D.1903, Feb. 2, 2022 Hr'g Tr. 33:15-16. The court then described its unprecedented certification of 111

economic loss subclasses plus two nationwide medical monitoring classes as just another step toward "promoting Class Action settlement." Opinion 41.

There is no way to try this case before a jury in a way that protects defendants' rights. No jury could individually evaluate the claims of 111 different economic loss subclasses and 31 defendants, after listening to *40 hours* of jury instructions. No jury could individually consider whether each of 31 defendants is subject to liability under 52 jurisdictions' laws, taking into account individualized differences among their products. And there is no way to address at trial the individual issue of whether each plaintiff is entitled to medical monitoring. By certifying a morass of subclasses never proposed by any party—without any indication of how this case could actually be tried—the district court created inordinate settlement pressure. For this reason, too, the Court should grant the petition.

## CONCLUSION

For the forgoing reasons, the Court should grant the petition.

Dated: February 22, 2023

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limit of Federal Rule of Appellate Procedure 5(c)(1) because, excluding parts of the petition exempted by Federal Rule of Appellate Procedure 32(f), it contains 5182 words, as counted by Microsoft Word, the word processing software used to prepare this brief. This petition also complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) as well as the typestyle requirements of Federal Rule of Appellate Procedure 32(a)(6), because it was prepared in a proportionally spaced typeface in 14-point Times New Roman font.

Dated: February 22, 2023

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## CERTIFICATE OF SERVICE

I hereby certify that on February 22, 2023, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Third Circuit by using the CM/ECF system. In addition, I hereby certify that on February 22, 2023, I served the foregoing document via email on all parties to the district court action in accordance with Federal Rule of Appellate Procedure 5(a)(1).

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In accordance with Third Circuit Local Rule 31.1(c), I hereby certify that a virus protection program, Symantec Endpoint Protection, has been run on the electronic version of the petition and no virus was detected.

I further certify that the text of the petition filed with the Court via CM/ECF is identical to the text in the paper copies filed with the Court.

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**CERTIFICATE OF BAR MEMBERSHIP**

In accordance with Third Circuit Local Rule 46.1(e), I hereby certify that I am a member in good standing of the Bar of the United States Court of Appeals for the Third Circuit.

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